国際予備審査報告

国際出願番号　ＰＣＴ／ＪＰ０２／１２７０８

Ⅴ．　新規性、進歩性又は産業上の利用可能性についての法第１２条（ＰＣＴ３５条(2)）に定める見解、それを裏付ける文献及び説明

１．　見解

新規性（N）　請求の範囲　1-7, 12　有
請求の範囲　9-11, 13, 14　無

進歩性（ＩＳ）　請求の範囲　1-7, 12　有
請求の範囲　9-11, 13, 14　無

産業上の利用可能性（ＩＡ）　請求の範囲　1-7, 9-14　有
請求の範囲　　無

２．　文献及び説明（ＰＣＴ規則70.7）

文献1：SUN, D. *et al*, Drug inhibition of Gly-Sar uptake and hPepT1 localization using hPepT1-GFP fusion protein, AAPS PharmaSci[online], 2001.01.11, Vol.3, No.1, E2, Retrieved from the Internet: <URL:http://www.aapspharmsci.org/view.asp?path=ps0301¥ps030102¥ps030102.xml&pdf=yes>
文献2：SAI, Yoshimichi *et al*, Immunolocalization and pharmacological relevance of oligopeptide transporter PepT1 in intestinal absorption of β-lactam antibiotics, FEBS Letters, 1996, Vol.392, No.1, pp25-29

新規性及び進歩性について
請求の範囲9-11, 13, 14について
文献1には、ヒト由来のPepT1に結合する抗体が記載されている（Material and Methods）。
ここで、本願明細書の第4頁の「本発明の細胞増殖抑制剤に含有される抗体はPepTと結合する限り特に制限はない」との記載を考慮すると、PepTに結合する抗体であれば全て細胞増殖抑制作用を有していると認められるので、文献1に記載の抗体もまた、当該作用を有しているものと推認される。
したがって、本願の請求の範囲9-11, 13, 14に係る発明は、文献1に記載されたものであるので、新規性及び進歩性を有しない。

請求の範囲9-11, 14について
文献2には、PepT1のC末端領域に結合する抗体が記載されている(Material and Methods)。　したがって、本願の請求の範囲9-11, 14に係る発明は、文献2に記載されたものであるので、新規性及び進歩性を有しない。

請求の範囲1-7, 12について
文献1及び2には、PepTに結合する抗体が細胞増殖抑制作用を有すること、及びPepTの細胞外領域に特異的に結合する抗体は記載がされていない。またそれらは当業者に自明であるとも認められない。よって本願の請求の範囲1-7, 12に係る発明は、国際調査報告に挙げたいずれの文献によっても新規性、進歩性は否定されない。

Translation

COPY SUBMITTED IN IDS

PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference C1-A0114P | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| International application No. PCT/JP02/12708 | International filing date (*day/month/year*) 04 December 2002 (04.12.02) | Priority date (*day/month/year*) 04 December 2001 (04.12.01) |
| International Patent Classification (IPC) or national classification and IPC A61K 39/395, A61P 35/00, 43/00, C07K 16/18, C12P 21/08 | | |
| Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 04 December 2002 (04.12.02) | 12 August 2003 (12.08.2003) |
| Name and mailing address of the IPEA/JP<br><br>Facsimile No. | Authorized officer<br><br>Telephone No. |

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP02/12708

## I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP02/12708

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 8

because:

☒ the said international application, or the said claims Nos. 8 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The subject matter of claim 8 relates to a method for treatment of the human body by therapy, which does not require an international preliminary examination by the International Preliminary Examining Authority in accordance with PCT Article 34 (4)(a)(i) and PCT Rule 67.1(iv).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 8 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP02/12708

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

The subject matter of claim 1 of the present application is considered to be "a cell proliferation inhibitor containing an antibody bound to PepT as an active ingredient," and the subject matter of claim 9 is considered to be "an antibody bound to PepT and having cytotoxic activity."

A matter common to the subject matters of claims 1-7 of the present application and to the subject matters of claims 9-14 is considered to be "an antibody bound to PepT," but as described in the following documents, the said antibody is publicly known. So, the said constitution is not considered to be a novel matter, and is not considered to be a major matter of the present invention.

It is not considered either that both the groups of claims are intended to solve a technically common problem not solved till the present application was filed.

Therefore, the subject matters of claims 9-14 of the present application and the subject matters of claims 1-7 are not considered to be a group of inventions so linked as to form a single general inventive concept.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-7, 9-14 .

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP02/12708

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-7, 12 | YES |
| | Claims | 9-11, 13, 14 | NO |
| Inventive step (IS) | Claims | 1-7, 12 | YES |
| | Claims | 9-11, 13, 14 | NO |
| Industrial applicability (IA) | Claims | 1-7, 9-14 | YES |
| | Claims | | NO |

2. Citations and explanations

Document 1: "Drug Inhibition of Gly-Sar Uptake and hPepT1 Localization Using hPepT1-GFP Fusion Protein," (D. Sun, et al.), AAPS PharmaSci [online], 11 January, 2001 (11.01.01), Vol. 3, No. 1, E2, Retrieved from the Internet: URL:http://www.aapspharmsci.org/view.asp?path=ps0301\ps030102\ps030102.xml&pdf-yes
Document 2: "Immunolocalization and Pharmacological Relevance of Oligopeptide Transporter PepT1 in Intestinal Absorption of β-lactam Antibiotics," (Yoshimichi Sai, et al.), FEBS Letters, 1996, Vol. 392, No. 1, pages 25-29

Novelty and Inventive Step:

Claims 9-11, 13 and 14

Document 1 describes an antibody bound to human-derived PepT1 (Material and Methods).

Considering the description on page 4 of the specification of the present application, "the antibody contained in the cell proliferation inhibitor of the present invention is not especially limited as far as it can be bound to PepT," since it is considered that all the antibodies bound to PepT have cell proliferation inhibitory action, the antibody described in document 1 can also be estimated to have the said action.

Therefore, the subject matters of claims 9-11, 13 and 14 do not appear to be novel or to involve an inventive step, since they are described in document 1.

Claims 9-11 and 14

Document 2 describes an antibody bound to the C-terminal region of PepT1 (Material and Methods). Therefore, the subject matters of claims 9-11 and 14 of the present application do not appear to be novel or to involve an inventive step, since they are described in document 2.

Claims 1-7 and 12

Documents 1 and 2 describe neither that an antibody bound to PepT has cell proliferation action, nor an antibody specifically bound to the extracellular region of PepT. These constitutions are not considered to be obvious to a person skilled in the art either. So, the subject matters of claims 1-7 and 12 appear to be novel and to involve an inventive step in view of the documents cited in the ISR.